

Remarks

Claims 1-37 were pending in this application. No claim amendments are made herein; therefore **claims 1-37 continue to be pending in this application.**

Restriction Requirement

Election

Claims 1-37 of this §371 National Stage application were indicated as being subject to a restriction requirement. Specifically, the Office action states that Groups 1-51 “are not so linked as to form a single inventive concept under PCT Rule 13.1.”

Under protest, and only to comply with 37 CFR §1.499, Applicants hereby elect, with traverse, Group 51 (corresponding to claim 37-in-part, directed to a peptide comprising peptide 41).

By the Office action, claim 37 is restricted into three different Groups directed to peptide 38, peptide 40, and peptide 41 (Groups 49, 50, and 51, respectively). Claim 37 is, in fact, directed to a “peptide comprising peptide 35, 38, 40, or 41.” However, none of the cited Groups include claim 37 (in part) directed to a *peptide comprising peptide 35*. Thus, Applicants respectfully request that the Examiner indicate in a subsequent Office communication that claim 37-in-part, directed to a peptide comprising peptide 35, is included in one of Groups 1-51 or, at a minimum, forms Group 52.

Applicants request rejoinder of Groups 50 and 51 (claim 37-in-part, directed to peptides 40 and 41) and claim 37-in-part, directed to peptide 35. Applicants submit that it is not an undue burden on the Examiner to examine peptides 35, 40, and 41 of claim 37 together, as they share several structural and functional characteristics.¹ For example, the specification provides evidence that peptides 35, 40, and 41 have an anti-proliferative effect on A549.tTA cells and the specification clearly describes that these peptides exhibit a similar anti-proliferative effect on a variety of cell types, including HeLa cells, Colo205 cells, H1299, MCF7, and normal human

¹ Peptide 35 is also referred to as peptide 88 in the specification; see page 2, line 9.

mammary gland epithelial cells (specification at page 55, lines 7-34; Figure 6). In addition, peptides 40 and 41 were shown to cause dose-dependent apoptosis and cell cycle arrest (specification at page 65, lines 1-17).

The specification also describes that peptides 35, 40, and 41 are significantly rich in arginine and hydrophobic amino acids, and that these peptides include a leucine-rich nuclear exclusion motif (specification at page 51, line 32 through page 52, line 7; page 63, line 33 through page 64, line 8; Table 3). Cellular localization studies of these peptides confirmed that they are all excluded from the nucleus (specification at page 63, lines 16-31). Moreover, peptides 35, 40, and 41 were shown to interact with an overlapping subset of cytoskeletal proteins (including tubulin, actin, and myosin), as well as an overlapping set of proteins involved in nucleocytoplasmic transport (including subunits of importin-beta, importin-alpha, exportin 1, and nucleoporin p62) (specification at page 65, line 18, through page 67, line 7; Table 7).

Thus, peptides 35, 40, and 41 have the following features in common:

- (i) nuclear exclusion;
- (ii) interaction with a common set of binding partners;
- (iii) sequence structure;
- (iv) inhibition of cellular proliferation; and
- (v) ability to influence cell cycle progression.

The similarity in structure, function, and cellular localization of these peptides, combined with the observed common set of binding partners, suggests that these peptides share a common mechanism of action. Accordingly, Applicants submit that it would not be an undue burden on the Examiner to search peptides 35, 40, and 41 together. Applicants respectfully request that the Examiner reconsider the Restriction Requirement and rejoin Groups 50 and 51, along with claim 37-in-part, directed to peptide 35.

Additional matters

Applicants expressly request that any method claims, which depend from or otherwise include all the limitations of claims directed to the peptide comprising peptide 41, be rejoined

and the claims examined, at the latest upon the allowance of any of the product claims. It is believed that this is in accordance with the current Patent and Trademark Office Guidelines for Restriction Requirements in TC1600.

In accordance with 37 CFR §1.143, Applicants reserve the right to petition to have the appropriateness of restriction of claim 37 (with respect to peptides 35, 40, and 41) reconsidered, if it is maintained in spite of this response.

Conclusion

It is believed that the application, with the Groups rejoined as requested above, is in condition for substantive examination. If any minor matters remain to be addressed prior to examination, the Examiner is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,

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